

### **REMARKS**

Upon entry of the foregoing amendment, claims 258-261, 267, 268, 270-272, 279-286, 290-315, 321, 322, 324-326, 333, 334, 337, 340, and 343 are pending in the application, with 258, 302, 334, and 340 being the independent claims. Claims 267, 268, 280-282, 290, 291, 293, 294, 301, 304, 305, 307, 308, 315, 321, and 333 have been withdrawn by the Examiner. Claims 262-266, 269, 273-278, 287-289, 316-320, 323, 327-332, 335, 336, 338, 339, 341, 342, 344, and 345 have been canceled without prejudice or disclaimer. Claims 258, 267, 268, 270, 271, 302, 321, 233, 324, 325, 334, 337, 340, and 343 have been amended to indicate that the claims are directed to compositions comprising bisphosphonate drugs. These changes are believed to introduce no new matter, and their entry is respectfully requested.

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

#### **Rejections Under 35 U.S.C. § 103**

(A) Claims 258-264, 266, 268, 275, 276, 278, 279, 283-286, 289, 292, 295, 296, 302, 303, 306, 309, 310, 316-318, 320, 322, 329, 330, 332, 334, 338-340, 344, and 345 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Watts *et al.* (International Application No. WO 97/05903) in view of Heiber *et al.* (U.S. Patent No. 5,346,701), and optionally any one or more of Teng *et al.* (U.S. Patent No. 6,747,014), Garces *et al.* (U.S. Patent No. 5,736,161), and Bachynsky *et al.* (U.S. Patent No. 5,190,748). (Office Action, page 3). Applicants respectfully traverse this rejection.

The Examiner states that in view of Applicants' Declaration of Thomas W. Leonard, Ph.D. Pursuant to 37 C.F.R. § 1.132 filed March 5, 2009, the rejection is not applicable to the claims that are directed to formulations comprising bisphosphonate drugs (*i.e.*, claims 269-272, 287, 323-326, 337, 342, and 343) but the other claims do not overcome the combined teachings in the art. (Office Action, page 3).

Applicants respectfully disagree with the position that the Declaration does not overcome the combined teachings in the art for claims to drugs other than bisphosphonates.

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Claims 262-264, 266, 275, 276, 278, 289, 316-318, 320, 329, 330, 332, 338, 339, 344, and 345 have been canceled, rendering that portion of the rejection moot. Applicants disagree with the Examiner regarding the obviousness of the present claims over the cited art.

However, in order to advance prosecution, the present claims have been amended to be directed to bisphosphonate drugs, which the Examiner has indicated is not obvious over the cited art. Thus, the rejection has been rendered moot.

It is respectfully requested that the rejection of claims 258-264, 266, 268, 275, 276, 278, 279, 283-286, 289, 292, 295, 296, 302, 303, 306, 309, 310, 316-318, 320, 322, 329, 330, 332, 334, 338-340, 344, and 345 be withdrawn.

(B) Claims 258-264, 266, 268, 275, 276, 278, 279, 283-286, 289, 292, 295-300, 302, 303, 306, 309, 310-314, 316-318, 320, 322, 329, 330, 332, 334, 338-340, 344, and 345 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Watts *et al.* (International Application No. WO 97/05903) in view of Heiber *et al.* (U.S. Patent No. 5,346,701), and optionally any one or more of Teng *et al.* (U.S. Patent No. 6,747,014), Garces *et al.* (U.S. Patent No. 5,736,161), and Bachynsky *et al.* (U.S. Patent No. 5,190,748), and further in view of Bürk *et al.* (U.S. Patent No. 5,221,734). (Office Action, page 7).

Applicants respectfully traverse this rejection.

The Examiner alleges that the teachings of the references cited in the previous rejection are incorporated herein and that Bürk *et al.* teaches formulations comprising the lubricant stearic acid and the disintegrant crospovidone. (Office Action, page 7).

Applicants respectfully disagree. Claims 262-264, 266, 275, 276, 278, 289, 316-318, 320, 329, 330, 332, 338, 339, 344, and 345 have been canceled, rendering that portion of the rejection moot. Applicants disagree with the Examiner regarding the obviousness of the present claims over the cited art. However, in order to advance prosecution, the present claims have been amended to be directed to bisphosphonate drugs, which the Examiner has indicated is not obvious over the cited art. Thus, the rejection has been rendered moot.

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It is respectfully requested that the rejection of claims 258-264, 266, 268, 275, 276, 278, 279, 283-286, 289, 292, 295-300, 302, 303, 306, 309, 310-314, 316-318, 320, 322, 329, 330, 332, 334, 338-340, 344, and 345 be withdrawn.

***Rejections for Double Patenting***

(A) Claims 258, 302, 269-272, 287, 323-326, 334, 337, 340, 342, and 343 have been provisionally rejected under 35 U.S.C. § 101 as claiming the same invention as that of the claims of copending Application Nos. 11/400,689 and 11/733,007. (Office Action, page 8). Applicants respectfully traverse this rejection.

Claims 269, 287, 323, and 342 have been canceled, rendering that portion of the rejection moot. Applicants respectfully assert that the present claims are not drawn to identical subject matter as the claims of Application No. 11/400,689. The claims of Application No. 11/400,689 as amended in the supplemental response filed August 6, 2009 are directed to compositions comprising a bisphosphonate selected from the group consisting of alendronate, clodronate, etidronate, incadronate, ibandronate, minodronate, parnidonate, risedronate, tiludronate and zoledronate. In contrast, the present claims are directed to any bisphosphonate. Thus, the claims of Application No. 11/400,689 necessarily differ in scope from the present claims and the statutory double patenting rejection is improper.

Moreover, Applicants respectfully assert that the present claims are not drawn to identical subject matter as the claims of Application No. 11/733,007. The claims of Application No. 11/733,007 are directed to compositions comprising specific dosages of alendronate and zoledronic acid. In contrast, the present claims are directed to any bisphosphonate and are not limited by specific dosages. Thus, the claims of Application No. 11/733,007 necessarily differ in scope from the present claims, and the statutory double patenting rejection is improper.

Applicants respectfully request that the rejection of claims 258, 302, 269-272, 287, 323-326, 334, 337, 340, 342, and 343 under 35 U.S.C. § 101 be withdrawn.

Should the Examiner be inclined to reject the present claims under obviousness-type double patenting, Applicants respectfully point that the rejection would be a provisional

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rejection because none of the claims of the co-pending application have yet been allowed. Applicants respectfully request that any such rejection be held in abeyance on this basis, with the understanding that, should claims issue in the co-pending application before allowable subject matter is identified in the present application, Applicants will address any double-patenting issue at that time.

(B) The Examiner states that claims 258, 302, 269-272, 287, 323-326, 334, 337, 340, 342, and 343 are directed to the same invention as that of the claims of commonly assigned 11/733,007 and that the issue of priority under 35 U.S.C. 102(g) and possibly 35 U.S.C. 102(f) of this single invention must be resolved. (Office Action, page 9).

Applicants respectfully assert that the present claims are not drawn to identical subject matter as the claims of Application No. 11/733,007. The claims of Application No. 11/733,007 are directed to compositions comprising specific dosages of alendronate and zoledronic acid. In contrast, the present claims are directed to any bisphosphonate and are not limited by specific dosages. Thus, the claims of Application No. 11/733,007 differ in scope from the present claims and the two applications do not relate to a single invention.

Furthermore, the subject matter of Application No. 11/733,007 and the presently claimed invention were, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person. Thus, there is no issue of priority under 35 U.S.C. 102(g) or 35 U.S.C. 102(f).

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### CONCLUSION

Accordingly, Applicants submit that the present application is in condition for allowance and the same is earnestly solicited. Should the Examiner have any small matters outstanding of resolution, he is encouraged to telephone the undersigned at 919-854-1400 for expeditious handling.

Respectfully submitted,



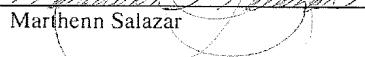
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### CERTIFICATION OF TRANSMISSION

I hereby certify that this correspondence is being transmitted via the Office electronic filing system in accordance with § 1.6(a)(4) to the U.S. Patent and Trademark Office on August 12, 2009.

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